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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,997	08/01/2003	Peiyuan Wang	09797.0002-00	8974
22852	7590	11/23/2009		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413				
EXAMINER				
PACKARD, BENJAMIN J				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
11/23/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/632,997

**Applicant(s)**

WANG ET AL.

**Examiner**

Benjamin Packard

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 15-17, 19, 26, 28, 29, 31 and 33-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 14, 18, 20-25, 27, 30 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1pg (9/24/09)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed 7/14/08 and 8/21/09, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Response to Election***

Applicant's election with traverse of the species of 1(T), as well as species 1(J) in the reply filed on 08/21/09 is acknowledged. The traversal is on the ground(s) that the MPEP only requires the election of "a single species" (see MPEP 808.01(a), 803.02, and 809.02(a)). This is not found persuasive because MPEP 803.02 states with regards to examination after a species election:

On the other hand, should \*\*>the examiner determine that< the elected species >is allowable<, the \*>examination< of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species.

Note, the last sentence suggests the search is not expanded beyond the next species rejected. Therefore, out of courtesy to Applicants in this case due to the change in Examiners, the current Examiner extended opportunity to Applicants to select the next species for examination.

**Claims 1-12** remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/03/07.

**Claims 15-17, 19, 26, 28, 29, 31, 33-37** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

**Claims 13, 14, 18, 20-25, 27, 30, 32** are now examined.

### ***Claim Objections***

**Claim 30** is objected to because of the following informalities:

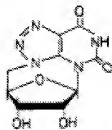
Claim 30 recites Z' and Z" may be CH, CX, or N. But the bond in the formula between them appears to be a single bond and no option is provided for a double bond, even though each disclosed option would require a double bond to fill valency. If the error is in the listing of the substituents for Z (i.e. Z is CH<sub>2</sub>, CX<sub>2</sub>, or NH), the claim will be properly withdrawn in the next action. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 13, 14, 18, 20-22, 25, 27, 30, 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al (J. Org. Chem., 1976, 41 (7), 1100-1104) in view of Patani et al (Chem. Rev. 1996, 96, 3147-3176).

Sasaki et al teaches compound 4:



which differs from 1(O) in that two oxygen are substituted on the 3,4-dihydropyrimidin-2(1H)-one ring rather than an oxygen and an amide, as instantly claimed (pg 1103). The compound has biological interest (abstract and pg 1100).

Patani et al teaches C=O and C=NH are isosteres and their substitution is common in chemical development (pg 3155 section B.1. Divalent Replacements Involving Double Bonds). Patani et al further teaches the hetero atom leads to tautomerization of these groups.

It would be obvious to one of ordinary skill in the art, when making the compounds of the primary reference to substitute known isosteres, such as disclosed in the secondary reference. The resulting compounds would then be expected be a tautomer where the -NH-C(=NH)- resonates to NH=C(-NH<sub>2</sub>)-, as recited in the compound 1(O).

Given that Compound 4 has biological activity and that compounds with biological activity are routinely made into pharmaceutical compositions with pharmaceutically acceptable carriers, it would be obvious to make a pharmaceutical composition of Compound 4 in a pharmaceutically acceptable carrier.

**Claims 23 and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al (J. Org. Chem., 1976, 41 (7), 1100-1104) in view of Patani et al (Chem. Rev. 1996, 96, 3147-3176), the combination further in view of Gilbert et al. (Antimicrobial Agents and Chemotherapy, 1986, Vol. 30, No. 2, pp. 201-205).

Sasaki et al and Patani et al do not teach the inclusion of an antiviral.

Gilbert et al teach nucleoside analogs are used as antiviral agents (page 201). Gilbert et al. further teach a specific nucleoside analog, ribavirin, has anti-viral activity and is used to treat a broad spectrum of DNA and RNA viruses (page 201). Gilbert et al. further disclose the clinical use of ribavirin in humans (page 202).

Gilbert et al does not teach the nucleoside analogs of Sasaki et al.

Given the teaching that nucleoside analogs have antiviral activity, it would be reasonably expected that the compounds made obvious by Sasaki et al and Patani et al would have the same functionality. Upon realizing the potential antiviral activity, it would be obvious to combine the agent with additional anti-viral agents. This position is consistent with well-established precedent holding that it is prima facie obvious to combine compositions known to be individually useful together so as to provide a third composition for the same use. See, e.g., In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980).

### ***Conclusion***

No claims allowed.

Note, compound 1(J) appears free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612